

Complete Summary

GUIDELINE TITLE

Opioid guidelines in the management of chronic non-cancer pain.

BIBLIOGRAPHIC SOURCE(S)

Trescot AM, Boswell MV, Atluri SL, Hansen NC, Deer TR, Abdi S, Jasper JF, Singh V, Jordan AE, Johnson BW, Cicala RS, Dunbar EE, Helm S II, Varley KG, Suchdev PK, Swicegood JR, Calodney AK, Ogoke BA, Minore WS, Manchikanti L. Opioid guidelines in the management of chronic non-cancer pain. Pain Phys 2006;9(1):1-39. [350 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
 METHODOLOGY - including Rating Scheme and Cost Analysis
 RECOMMENDATIONS
 EVIDENCE SUPPORTING THE RECOMMENDATIONS
 BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
 QUALIFYING STATEMENTS
 IMPLEMENTATION OF THE GUIDELINE
 INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
 CATEGORIES
 IDENTIFYING INFORMATION AND AVAILABILITY
 DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Chronic non-cancer pain

GUIDELINE CATEGORY

Evaluation
 Management
 Treatment

CLINICAL SPECIALTY

Anesthesiology
Internal Medicine
Neurology
Psychiatry
Rheumatology

INTENDED USERS

Health Care Providers
Physicians

GUIDELINE OBJECTIVE(S)

- To bring consistency in opioid prescribing to the many diverse groups involved
- To provide analysis of evidence to treat a chronic pain patient with opioids, thus, maintaining reasonable patient access while reducing the risk of drug diversion
- To provide practical prescribing guidelines for physicians to reduce the risk of legal and regulatory sanctions
- To emphasize the need for systematic evaluation and ongoing care of patients with chronic or persistent pain

TARGET POPULATION

All patients suffering with chronic non-cancer pain who may be eligible for appropriate, medically necessary management

INTERVENTIONS AND PRACTICES CONSIDERED

Use of Opioid Therapy for Management of Chronic Pain

1. Screening for opioid abuse
 - Urine drug testing (immunoassay, gas chromatography/mass spectrometry), high performance liquid chromatography)
2. Periodic review and adherence monitoring
 - Periodic review of diagnosis and appropriateness of therapy
 - Periodic monitoring of patient compliance in medication usage
 - Prescription drug monitoring
 - Periodic education for physicians, providers, and patients
 - Pill counts
3. Evaluation
 - Patient history (pain, medical, and psychosocial)
 - Effect on functional status
 - Drug history
4. Physical examination
5. Laboratory studies (x-rays, other imaging studies, electrophysiological studies, blood work)
6. Psychological evaluation
7. Medical decision making and treatment plan
8. Consultation/referral

9. Obtaining informed consent and controlled substance agreement
10. Documentation and medical records

MAJOR OUTCOMES CONSIDERED

- Effectiveness and adverse effects of opioids in the treatment of chronic pain
- Sensitivity of drug testing assays for opioids
- Prevalence of controlled prescription drug abuse
- Prevalence of drug diversion

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Electronic database searches include PubMed and EMBASE.

NUMBER OF SOURCE DOCUMENTS

The authors utilized two systematic reviews, two narrative reviews, 32 studies included in prior systematic reviews, and 10 additional studies in the synthesis of evidence.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Designation of Levels of Evidence

Level I

Conclusive: Research-based evidence with multiple relevant and high-quality scientific studies or consistent reviews of meta-analyses

Level II

Strong: Research-based evidence from at least one properly designed randomized, controlled trial; or research-based evidence from multiple properly designed studies of smaller size; or multiple low quality trials

Level III

Moderate: a) Evidence obtained from well-designed pseudorandomized controlled trials (alternate allocation or some other method); b) evidence obtained from comparative studies with concurrent controls and allocation not randomized (cohort studies, case-controlled studies, or interrupted time series with a control group); c) evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group

Level IV

Limited: Evidence from well-designed nonexperimental studies from more than one center or research group; or conflicting evidence with inconsistent findings in multiple trials

Level V

Indeterminate: Opinions of respected authorities, based on clinical evidence, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

In synthesizing the evidence, systematic reviews, randomized clinical trials, and observational studies were evaluated utilizing reporting criteria and quality evaluation criteria. If the available systematic reviews met the criteria of inclusion, only those studies published after the publication date of the systematic reviews were evaluated.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A policy committee was convened and included a broad representation of academic and clinical practitioners recognized as experts in one or more aspects of opioids, and representing a variety of practices and geographic areas. This committee formalized the essentials of the guidelines. This was followed by the formulation of a series of potential evidence linkages representing conclusions and statements about relationships between clinical interventions and outcomes. The elements of the guideline preparation process included literature searches, literature syntheses, systematic review, consensus evaluation, open forum presentations, formal endorsement by the American Society of Interventional Pain Physicians (ASIPP) Board of Directors and blinded peer review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Adherence Monitoring

Introduction

Important issues in opioid therapy for the treatment of chronic pain revolve around the appropriate use of prescription opioids. Consequently, adherence monitoring is crucial to avoid abuse of the drugs and at the same time to encourage appropriate use. Adherence monitoring is achieved by screening tests, urine drug testing, and periodic monitoring.

Confusion surrounding a specific operational definition of opioid misuse among chronic pain patients has complicated the process of effectively assessing and predicting its occurrence.

Screening for Opioid Abuse

Even though several investigators have described multiple screening instruments in detecting opioid abuse or misuse in chronic pain patients, there is no widely used screening instrument in current practice. A summary description of key criteria in the literature is shown in table 11 of the original guideline document.

Based on the multiple criteria utilized and their validation, the following may be used to indicate potential abuse or inappropriate use of opioids in clinical practice: 1) excessive opioid needs; 2) deception or lying to obtain controlled substances; 3) doctor shopping; 4) nonfunctional status; 5) exaggeration of pain; and 6) prescription forgery.

Urine Drug Testing

Drug testing may be performed by either testing the urine, serum, or hair. However, urine is considered to be the best biologic specimen for detecting the

presence or absence of certain drugs due to specificity, sensitivity, ease of administration, and cost. However, controversies exist regarding the clinical value of urine drug testing, partly because the most current methods are designed for, or adapted from, forensic or occupational deterrent-based testing for illicit drug use and are not necessarily optimized for clinical applications in chronic pain management. However, in chronic pain management, when used with an appropriate level of understanding, urine drug testing can improve a physician's professional ability to manage therapeutic prescription drugs with controlled substances, and to diagnose substance abuse or appropriate intake of drugs, thereby leading to proper treatment.

In principle, urine drug tests can detect the parent drug and/or its metabolite(s) and, therefore, demonstrate recent use of prescription medications and illegal substances. For most clinical applications, initial testing is done with class-specific immunoassay drug panels that typically do not identify individual drugs within a class. However, this may be followed by a more specific technique such as a gas chromatography/mass spectrometry (GC/MS) to identify, or confirm the presence, or absence, of a specific drug and/or its metabolite(s). Numerous differences exist between various tests and even among the testing laboratories and manufacturers of various rapid drug screen tests, including the number of drugs tested, cross-reactivity patterns, cut-off concentrations, and drug interferences. Consequently, clinicians should remember that the cut-off concentrations used for drugs in federally-regulated testing, particularly opioids, are too high to be of value in clinical practice. Federally regulated testing includes the five drugs or drug classes tested for in federal employees and employees of federally-regulated industries. The five include marijuana, cocaine, opiates, PCP, and amphetamines/methamphetamines, with pre-determined cut-off levels with mandatory reconfirmation of results by GC/MS, along with split sample in chain of custody requirements. In contrast, non-regulated testing is used for many purposes, including monitoring patients clinically.

In clinical practice, urine drug testing is used for accurate record keeping, to identify use of undisclosed substances, to uncover diversion or trafficking, and to determine appropriate intake of prescribed substances. There are typically two types of urine drug testing. These approaches used in proper combination can reduce cost, ensure accuracy, and improve efficiency. The two main types of urine drug testing methods are:

1. Immunoassay drug testing, either laboratory based or by rapid drug testing
2. Laboratory-based specific drug identification with GC/MS, high-performance liquid chromatography (HPLC), etc.

Refer to the original guideline document for a discussion of drug-testing methods.

Table 12 in the original guideline document illustrates cut-off levels for various drugs detected by urine analysis. Ideally, in chronic pain management settings a panel for rapid drug screening should include not only opiates, but also oxycodone and methadone. In addition, the panel should include cocaine, marijuana, amphetamines and methamphetamines for illicit drugs, and benzodiazepines and barbiturates for other controlled substances. If a custom panel is not available, multiple tests may have to be performed as rapid drug screening. Since false-negatives and false-positives are possible, when questions arise, prior to taking

any actions, a confirmatory test or no-threshold test must be performed in the laboratory.

Note that detection times can vary considerably, depending upon acute versus chronic use, the particular drug used within a class, individual characteristics of the patient, and the method used to test for a substance.

Physicians should establish a policy regarding their response to a positive drug screen. This may include referral to an addictionologist or psychologist, or may result in the refusal to prescribe opioids. However, it usually does not warrant dismissal of the patient. Furthermore, a policy regarding inappropriate use of prescription drugs provided by the physician, as well as doctor shopping, also should be addressed systematically and consistently. Interpretation of drug screens must include knowledge of the opioid metabolites. For example, a urine screen positive for hydromorphone in a patient receiving hydrocodone reflects not drug abuse but the appropriate metabolism of hydrocodone. In the same way, since codeine is metabolized to morphine, a screen positive for morphine in a patient taking codeine would be expected. Physicians not familiar with the opioid metabolites have wrongly accused too many patients of drug abuse.

Periodic Review and Monitoring

Periodic Review

Periodic reviews should assess: the medical diagnoses; psychological diagnoses; informed consent; treatment agreement; appropriate opioid therapy with or without adjuvant medications or with or without interventional techniques; pre and post intervention assessment of pain level and function; and reassessment of pain score and level of function.

Regular assessment of the patient along with the periodic review of the diagnosis is extremely important. Routine assessment of the "4 As" (analgesia, activity, aberrant behavior, and adverse effects) will help to direct therapy and support the pharmacologic actions taken.

Further assessment should be performed by periodic monitoring, utilizing drug screening tests, and urine drug testing.

Periodic Monitoring

At reasonable intervals, depending on the specific circumstances of a given patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress towards stated treatment goals, such as a reduction in a patient's pain scores and improved physical and/or psychosocial function (i.e., ability to work, utilization of healthcare resources, activities of daily living, and quality of social life). If treatment goals are not being achieved despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment with the current medications. The physician should monitor patient compliance in medication usage and related treatment plans.

Prescription Drug Monitoring

Prescription monitoring programs are changing as the result of recently enacted National All Schedules Prescription Electronic Reporting Act (NASPER) legislation that will assist physicians and pharmacists in identifying controlled substance abuse. While some existing monitoring programs intend to support state laws to ensure legitimate access to drugs, while preventing illegal diversion, many represent information collected to assist state law enforcement and regulatory agents in identifying and investigating illegal practices related to controlled substances.

NASPER legislation will allow for electronic sharing of information across state lines, with physicians and pharmacists as primary users of the system. State by state development of NASPER programs will allow for electronic sharing of information across state lines and will ultimately replace most of the current prescription monitoring programs. Current programs generally involve either use of multiple-copy prescriptions or electronic transmission. Multiple-copy prescription programs require physicians to use state-issued duplicate copy prescription pads that contain serial numbers. After a prescription is filled, one copy of the prescription form is sent to a state regulatory agency. However, in recent years these programs have increasingly been replaced by electronic variations that require pharmacists to transmit prescription information via computer to a designated state agency.

Physicians can use these prescription programs to their advantage in monitoring patients. Monitoring can be achieved by initial assessment followed by intermittent assessment of a patient's drug profile. However, if abuse is suspected or the physician's office receives complaints from family, friends, neighbors, law enforcement, appropriate action should be taken, along with frequent monitoring.

Periodic Education

Drug education for physicians, providers, and patients is crucial. While it appears that certain medications have revolutionized the treatment of chronic pain in the United States, physicians must balance medical need with the possibility of abuse and diversion, as well as the necessity to comply with state and federal regulations. It is obvious that healthcare practitioners are not only expected to prescribe medications when there is medical need and document appropriately, but they are also expected to prevent illegal diversion and identify drug abuse. Consequently, education is a critical component of any program to control the diversion of prescription drugs.

However, data shows that many physicians get little to no training regarding drug abuse. A 1999 survey of primary care physicians found there was a general lack of training in medical schools about addiction and the signs of substance abuse. This survey revealed that 46.6% of physicians had difficulty discussing prescription drug abuse with patients, and only 32.1% carefully screened their patients for substance abuse. This leads to difficulty discussing substance abuse with patients and an inability to recognize the signs of addiction. Figure 8 in the original guideline document shows that the majority of the physicians surveyed did not feel "very prepared" to diagnose substance abuse.

The educational aspects have been improving gradually. The American Society of Interventional Pain Physicians (ASIPP) assists in preventing diversion while maintaining the availability of prescription drugs for medical treatment. ASIPP has devised guidelines for the use of controlled substances in the management of pain, which include information on how to conduct a comprehensive evaluation to select patients for drug therapy and how to use a "controlled substance agreement" as part of patient care. Other ASIPP activities have included actions and support leading to the passage of the NASPER for uniform drug monitoring programs across the states with interstate communication and physician access to the monitoring programs. In addition, the American Board of Interventional Pain Physicians has made a competency certification available for interested physicians. Other organizations involved in substance abuse training include the American Academy of Family Physicians which has taken steps to make physicians aware of practices such as doctor shopping, and the American Society of Addiction Medicine which conducts seminars and also provides certification in addiction management.

Additionally, several states have taken steps to educate physicians about prescription drugs.

Pill Counts

Random pill counts, along with urine drug testing and prescription monitoring, would greatly reduce controlled substance abuse and diversion. Pill counts are essential in patients suspected of abuse. However, these can also be performed randomly on high risk patients.

A pill count is performed by notifying the patient a day before or on the day of the patient's appointment that they are requested to bring any unused pills to the appointment. Inability to provide pills, or providing a reduced number, will indicate use beyond the prescription. Pill counts above expected ranges would indicate inappropriate intake. Recently, it has been reported that unsuspecting elderly patients may be selling their prescriptions of controlled substances to supplement their incomes.

Principles Of Opioid Use

Introduction

In interventional pain management, patients may receive not only opioid analgesics, but also other controlled or noncontrolled drugs. Further, patients may be receiving controlled substances as an adjunct to interventional techniques, as well as to manage comorbid psychiatric and psychological disorders. Thus, the effectiveness studies published may not apply in the majority of cases in interventional pain management. Indeed, controlled substances, particularly opioid analgesics, may be prescribed at lower doses to maintain functional status in conjunction with interventional techniques. It has also been shown that interventional techniques reduce psychological distress significantly once the pain improves. More likely than not, the requirement for opioids and adjuvant drugs may be reduced. Hence, interventional pain physicians probably should not compare the patients in their settings who are undergoing interventional techniques with others who are receiving drug therapy as a mainstay.

Monotherapy, particularly with opioids, may be appropriate for only a small subgroup of those with chronic pain.

Basic Philosophy

Principles for prescribing opioids must require a comprehensive evaluation (mandatory physical and optional psychological), appropriate documentation at regular intervals to assess the efficacy of therapy, with specific evaluation of the impact on functional status, degree of pain relief, identification and treatment of undesirable side effects, and monitoring for abuse behaviors. In addition, there must be adherence to a controlled substance agreement and with regulatory guidelines promulgated by various agencies. Figure 9 in the original guideline document shows an algorithmic approach to patient evaluation and management. The table below also shows an algorithmic approach for chronic opioid therapy.

Table. Ten Step Process: An Algorithmic Approach for Long-Term Opioid Therapy in Chronic Pain

STEP I	Comprehensive initial evaluation
STEP II	Establish diagnosis <ul style="list-style-type: none"> • X-rays, magnetic resonance imaging (MRI), computed tomography (CT), neuro-physiological studies • Psychological evaluation • Precision diagnostic interventions
STEP III	Establish medical necessity (lack of progress or as supplemental therapy) <ul style="list-style-type: none"> • Physical diagnosis • Therapeutic interventional pain management • Physical modalities • Behavior therapy
STEP IV	Assess risk-benefit ratio <ul style="list-style-type: none"> • Treatment is beneficial
STEP V	Establish treatment goals
STEP VI	Obtain informed consent and agreement
STEP VII	Initial dose adjustment phase (up to 8-12 weeks) <ul style="list-style-type: none"> • Start low dose • Utilize opioids, nonsteroidal anti-inflammatory drugs (NSAIDs) and adjuvants • Discontinue due to <ul style="list-style-type: none"> • Lack of analgesia • Side effects • Lack of functional improvement

STEP VIII	Stable phase (stable - moderate doses) <ul style="list-style-type: none"> • Monthly refills • Assess for four As <ul style="list-style-type: none"> • Analgesia • Activity • Aberrant behavior • Adverse effect • Manage side effects
STEP IX	Adherence monitoring <ul style="list-style-type: none"> • Prescription monitoring programs • Random drug screens • Pill counts
STEP X	Outcomes <ul style="list-style-type: none"> • Successful - continue <ul style="list-style-type: none"> • Stable doses • Analgesia, activity • No abuse, side effects • Failed - discontinue if <ul style="list-style-type: none"> • Dose escalation • No analgesia • No activity • Abuse • Side effects • Non-compliance

Evaluation

Appropriate history, physical examination, and medical decision-making based on the initial evaluation of a patient's presenting symptoms are essential. Guidelines by the Centers for Medicare and Medicaid Services (CMS) provide various criteria for five levels of service. The three crucial components of evaluation and management services are: history, physical examination, and medical decision-making. Other components include counseling, coordination of care, nature of the presenting problem, and time required for face-to-face evaluation. While there are numerous techniques to evaluate a chronic pain patient, and these vary from physician to physician, institution to institution, and textbook to textbook, following the guidelines established by CMS will assist a physician in performing a comprehensive and complete evaluation while complying with regulations.

History

The history includes the chief complaint, history of the present illness, review of systems, and past, family, and/or social history.

History of the present illness is a chronological description of the development of a patient's present illness from the first sign and/or symptom. It includes multiple elements: location; quality, severity, duration, timing, context, and modifying factors; and associated signs and symptoms.

Review of systems is an inventory of body systems obtained through a series of questions seeking to identify signs and/or symptoms that the patient may be experiencing or has experienced.

Past, family, and/or social history is crucial for chronic pain patients who may be treated with opioids. It consists of a review of the past history of the patient, including past experiences, illnesses, operations, injuries, and treatment; family history, including a review of medical events in the patient's family, hereditary diseases, and other factors; and social history appropriate for age reflecting past and current activities.

Past history in interventional pain management includes history of past pain problems; motor vehicle, occupational, or non-occupational injuries; history of various pain problems; disorders such as arthritis, fibromyalgia, systemic lupus erythematosus; drug dependency, alcoholism, or drug abuse; and psychological disorders such as depression, anxiety, schizophrenia, suicidal tendencies, etc.

Family history is also important, and should include not only the history of different pain problems, including degenerative disorders, but also should include familial disorders, drug or chemical dependency, alcoholism, or drug abuse and psychological disorders such as depression, anxiety, schizophrenia, and suicidal tendencies, etc., specifically in first degree relatives.

Social history is also of crucial importance in administering opioids, including environmental information, education, marital status, children, habits, hobbies, occupational history, family support system, and recreational drug usage.

Effect on Functional Status

Some of the aspects specific in controlled substance abuse and chronic pain include evaluation of effect of pain on physical and psychological function, such as activities of daily living.

Drug History

It is important to obtain a patient drug profile, including drug history and family history of drugs, and other chronic pain patients in the patient's social circles. It is also important to obtain a pre-drug screening prior to embarking on opioid therapy in conjunction with obtaining a patient's opinion with regards to the doses of controlled substances, the importance of adherence, and its monitoring.

Physical Examination

Physical examination involves general, musculoskeletal, and neurological examinations. Examination of other systems, specifically cardiovascular,

lymphatic, skin, eyes and cranial nerves is recommended based on the presenting symptomatology.

Laboratory Studies

To complement the history and physical examination, a review of the records, either previous records or various investigations, must be obtained or new investigations must be ordered as appropriate. These include multiple radiological studies such as x-rays, magnetic resonance imagings (MRIs), computed tomography (CT), bone scan, etc.; electrophysiologic studies such as electromyography (EMG) and nerve conduction studies; and blood work.

Psychological Evaluation

Psychological evaluation is an extension of the evaluation process similar to the laboratory evaluation, imaging techniques, electromyography and nerve conduction studies.

By definition, pain is a subjective description of the patient's perception of actual or potential tissue damage. The distinction between pain and suffering should be established. A patient may suffer due to pain, but may have other reasons for suffering as well. The assessment of a patient's overall condition should be made at the initial evaluation and frequently thereafter. It is the goal of the physician to assist in the relief of suffering, no matter the cause. Financial, emotional, mental, physical, and spiritual factors may contribute to the patient's suffering. Relief of the underlying causes of suffering, as well as the pain, will lead to optimal treatment and utilization of controlled substances.

Medical Decision Making and Treatment Plan

Medical decision making refers to the complexity of establishing a diagnosis and/or selecting a management option, including providing controlled substances to a patient, and is measured by three components: diagnosis/management options with a number of possible differential diagnoses and/or the number of management options; review of records/investigations, with number and/or complexity of medical records, diagnostic tests, and other information that must be obtained, reviewed, and analyzed; and risks of significant complications, morbidity and mortality, as well as comorbidities associated with the patient's presenting problem(s), the diagnostic procedures, and/or the possible management options.

Prior to embarking on a regimen of opioids, the physician must determine, through actual clinical trial or through patient records and history, that non-addictive medication regimens and/or interventional techniques have been inadequate or are unacceptable for solid, clinical reasons. If this information is not available entirely through the patient, a family conference may be helpful to evaluate the patient's integrity. However, because of Health Insurance Portability and Accountability Act (HIPAA) regulations, the ability to have family conferences may be limited. An extensive drug utilization history of the patient must be documented through previous medical records, state drug monitoring programs, and multiple other avenues.

Diagnostic interventional techniques will assist in making the proper diagnosis by following an algorithmic approach. It has been shown that in approximately 70% to 85% of patients with spinal pain an accurate diagnosis may not be determined in spite of the available history, physical examination, EMG nerve conduction studies, and radiological evaluation. With precise diagnostic interventional techniques, the chances of diagnosis may be improved substantially, and proper treatment may be offered.

Therapeutic interventional techniques also may be used as a monotherapy rather than using opioids for pain management and functional improvement. The effectiveness of various interventional techniques has been evaluated in systematic reviews.

A written treatment plan should document objectives that will be used to evaluate treatment success, including pain relief and improved physical and psychosocial function, and should indicate if additional diagnostic tests, consultations, or treatments are planned. After starting treatment, the physician should carefully adjust the drug therapy to the individual medical needs of each patient. In the continuum of treatment, other modalities including interventional techniques, rehabilitation, and psychological therapy may be necessary depending on the etiology of pain and the extent to which pain is associated with physical, functional, and psychosocial impairment.

Consultation

To achieve treatment objectives, physicians should be willing to refer a patient for additional evaluation as clinically indicated. Special attention should be given to those patients who are at risk of misusing their medications and those whose living arrangements create a risk for medication misuse or diversion. The management of patients with a history of substance abuse or with a coexisting psychiatric disorder may require extra care, monitoring, documentation, and consultation with, or referral to, an addictionologist. The lack of well-trained psychologists and psychiatrists in many regions of the country may make this referral difficult to obtain. In many locations there are no clinically trained addiction specialists with whom to collaborate.

Informed Consent and the Controlled Substance Agreement

At the outset, the physician should discuss the risks and benefits of the use of controlled substances with the patient or surrogate, including the risk of tolerance and drug dependence. It is advisable to employ the use of a written agreement between physician and patient outlining patient responsibilities. Agreements are helpful, specifically if the patient is determined to be at high risk for medication abuse or has a history of substance abuse. Possible items of a controlled substance agreement between a physician and patient include:

1. One prescribing doctor and one designated pharmacy
2. Urine/serum drug screening when requested
3. No early refills and no medications can be called in. If medications are lost or stolen, then a police report could be required before considering additional prescriptions.

The reasons for which opioid drug therapy may be discontinued should be delineated, such as violation of a documented doctor/patient agreement. Additional items to be included in an agreement are listed in Figure 10 of the original guideline document.

Documentation and Medical Records

The physician should keep accurate and complete medical records which include all aspects of interventional pain management and medical care. These comprise, but are not limited to:

- The medical history and physical examination
- Diagnostic, therapeutic, and laboratory results
- Evaluations and consultations
- Treatment objectives
- Discussion of risks, benefits, and limitations of treatments
- Details of different treatments and medications, including date, type, dosage, and quantity prescribed
- Instructions to the patient
- Periodic reviews of outcomes, including documentation of functional status, preferably using validated tools

Records should remain current and be maintained in an accessible manner and readily available for review, not only for the physician and other members of the practice, but also the authorities.

To be in compliance with controlled substance laws and regulations required to prescribe, dispense, or administer controlled substances, the physician must have an active license in the state and comply with applicable federal and state regulations. Various boards have published regulations and recommendations for prescribing controlled substances. Physicians are advised to refer to these regulations for their respective state.

Physicians, under all circumstances, except for unavoidable emergencies, should not prescribe scheduled drugs for themselves, immediate family, or staff.

The following criteria should be considered carefully in providing controlled substances:

1. Complete initial evaluation, including history and physical examination
2. Psychological evaluation
3. Physiological and functional assessment, as necessary and feasible
4. Definition of indications and medical necessity:
 - Pain of moderate-to-severe degree
 - Suspected organic problem
 - Failure to respond to noncontrolled substances, adjuvant agents, physical therapy, and interventional techniques
 - Patients with interventional techniques as primary modality and controlled substance drugs as a second line treatment.
 - Responsiveness to prior interventions with improvement in physical and functional status for continued management, with or without interventions, must be documented.

- For non-opioid controlled substances, appropriate documentation of psychological disorders should be maintained.
 - Continued opioid prescriptions require monitoring of:
 - Analgesia
 - Activity
 - Aberrant behavior
 - Adverse effects
5. Adherence to the controlled substance agreement with the patient understanding the risks and benefits of controlled substances and the policy and regulations of the practitioner, including controlled substances being prescribed by only one practitioner and being obtained from only one pharmacy.
 6. Monitoring for drug abuse or diversion should be routine and, if confirmed, referral to rehabilitation centers may be made, along with termination of prescriptions for controlled substances.

KEY POINTS

1. Opioid guidelines for the treatment of chronic non-cancer pain are developed to improve quality and appropriateness of care, improve patient access, improve patient quality of life, improve efficiency and effectiveness, and achieve cost containment by improving the cost-benefit ratio.
2. Rationalization and importance of these guidelines derives from the fact that most available evidence documents a wide degree of variance in the prescribing patterns of opioids for chronic pain. The strength of available evidence for the use of opioids for chronic non-cancer pain remains Limited, Level IV.
3. Opioids are extensively used in managing chronic pain.
4. There is significant evidence of opioid abuse in conjunction with or without illicit drugs.
5. Abuse terminology is variable. This document attempts to standardize and provide common sense definitions.
6. Opioid pharmacology is variable but understanding it is essential to proper management of patients.
7. Among the rules of opioid administration, comprehensive evaluation and diagnostic assessment are crucial, including diagnosis by interventional techniques.
8. Establishing goals of treatment and using a controlled substance agreement are essential in the practice of pain management with opioids.
9. Periodic review of the patient on opioids is essential, using appropriate adjustments, with routine assessment of analgesia, activity, aberrant behavior, and adverse effects.
10. Documentation is essential, including the need to keep accurate and complete medical records with all the essential elements to provide proper patient care and also meet regulatory and legal requirements.

CLINICAL ALGORITHM(S)

A clinical algorithm is provided in the original guideline document for evaluation and management of chronic pain.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations was not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The perceived benefits of these guidelines include:

- Improved patient compliance
- Improved patient care with appropriate medical management
- Reduced misconceptions among providers and patients about opioids
- Improved ability to manage patient expectations
- Reduced abuse and diversion
- Improved cooperation among patients, providers, and regulatory agencies.

POTENTIAL HARMS

- There is significant evidence of opioid abuse in conjunction with or without illicit drugs.
- While advocacy for appropriate opioid usage in chronic pain continues, it is well known that prolonged use of opioids may result in adverse consequences, including tolerance, hyperalgesia, hormonal effects, and immunosuppression. Sections 4.3-4.6 of the original guideline document discuss adverse effects and drug interactions of opioids in detail.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines do not constitute inflexible treatment recommendations. It is expected that a provider will establish a plan of care on a case-by-case basis, taking into account an individual patient's medical condition, personal needs, and preferences, as well as the physician's experience. Based on an individual patient's needs treatment different from that outlined here could be warranted. These guidelines do not represent a "standard of care."
- These guidelines focus on the effective management of chronic non-cancer pain as well as the multiple issues related to opioid administration. It is recognized that management of chronic non-cancer pain takes place in a wide context of healthcare involving multiple specialists and multiple techniques. Consequently, the decision to implement a particular management approach should be based on a comprehensive assessment of the patient's overall health status, disease state, patient preference, and physician training and skill.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Clinical Algorithm

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Trescot AM, Boswell MV, Atluri SL, Hansen NC, Deer TR, Abdi S, Jasper JF, Singh V, Jordan AE, Johnson BW, Cicala RS, Dunbar EE, Helm S II, Varley KG, Suchdev PK, Swicegood JR, Calodney AK, Ogoke BA, Minore WS, Manchikanti L. Opioid guidelines in the management of chronic non-cancer pain. Pain Phys 2006;9(1):1-39. [350 references]

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [American Society of Interventional Pain Physicians Web site](#).

Print copies: Available from the American Society of Interventional Pain Physicians, 2831 Lone Oak Road, Paducah, KY 42003; Phone: (270) 554-9412; Fax: (270) 554-8987; email: asipp@asipp.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Sample controlled substance agreement. Figure 10 of the guideline document, available from the [American Society of Interventional Pain Physicians Web site](#).

PATIENT RESOURCES

None available

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